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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,997	01/16/2004	Michael Nyle Hershberger	P155	7917

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER

SCHLENTZ, NATHAN W

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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04/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/758,997	Applicant(s) HERSHBERGER, MICHAEL NYLE	
	Examiner Nathan W. Schlientz	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 27-33 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 8-14, 27-33 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 February 2009 has been entered.

Status of Claims

Claims 1-19, 27-33 and 39 are pending in the present application. Claims 8-14, 27-33 and 39 are withdrawn from further consideration as being drawn to non-elected subject matter. Therefore, claims 1-7 and 15-19 are examined herein on the merits for patentability to the extent that they read on the elected subject matter of record. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (US 2002/0025325) in view of Burkhalter et al. (The Journal of Nutrition, 2001), Sunvold et al. (Journal of Animal Science, 1995), Fahey et al. (Journal of Animal Science, 1990), Sunvold '258 (US 5,932,258), Jezek et al. (Chemical and Biochemical Engineering Quarterly, 1996), and Desforges et al. (US 5,252,136).

Applicant's claims

Applicants claim a liquid composition comprising lufenuron, a flavorant and water, wherein the composition is essentially free of sugars or tomato flavor.

Determination of the scope and content of the prior art

(MPEP 2141.01)

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Chu et al. teach compositions for oral vaccination of healthy animals through drinking water or syrups comprising admixing a palatable flavorant with a vaccine formulation in order to promote self-administration of the vaccine formulation and/or to prevent rejection of the formulation when administered by an animal handler (Abstract). Chu et al. teach an example wherein the lyophilized vaccine is re-suspended in a flavored diluent, mixed with 5 liters milk solution containing non-fat dry milk, and then further diluted with 7 liters of water ([0102]). Also, Chu et al. teach that flavorants for use in the vaccine formulations include fruit flavors preferred for horses, cats and dogs, meat flavors preferred for dogs and cats, and fish flavors preferred for cats ([0029]).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Chu et al. do not teach the addition of beet pulp to their composition, as instantly claimed. However, Burkhalter et al. teach that beet pulp is the most common source of fiber added to commercial dog diets (page. 1979, left column, lines 8-10 after the table description). Sunvold et al. teach that diets containing moderately fermentable fiber provide fermentation end products that may be important in maintaining the health of the gastrointestinal tract of the cat, and beet pulp represents a moderately fermentable fiber source (Abstract; pg. 2335, left column, last sentence; pg. 2338, left column, lines 40-55 without counting spaces). Fahey et al. teach beet pulp levels up to 7.5% of diet DM appear acceptable as a dietary fiber source in a meat-based canine diet (Abstract). Sunvold '258 teach beet pulp is a fermentable fiber which intestinal bacteria present in the animal can ferment to produce significant quantities of short-chain fatty acids (col. 3,

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II. 48-54). Jezek et al. teach the production of soluble dietary fibers from sugar beet pulp (Title and Abstract). Desforges et al. teach water-soluble fiber obtainable by treating sugar beet with water free from chemical reagents at ambient temperature and at an elevated temperature (Abstract). Desforges et al. further teach that commercial sources of dietary fiber from sugar beet pulp are known, wherein araban is one example of a fraction of the soluble fiber from sugar beet, and water-soluble beet fiber is also found in beet molasses (col. 1, l. 55 to col. 2, l. 5). Desforges et al. also teach that soluble sugar beet fiber has cholesterol lowering properties (i.e., hypocholestromaemic effect), and a beneficial effect on blood glucose and mineral availability (col. 2, II. 13-17).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to add beet pulp fiber to the composition of Chu et al. because beet pulp fiber is well-known as a commercial source of dietary fiber for use in pet foods, and soluble beet fiber has cholesterol lowering properties (i.e., hypocholestromaemic effect), and a beneficial effect on blood glucose and mineral availability, as reasonably taught by Desforges et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to

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one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on page 9 that Burkhalter et al., Sunvold et al., Fahey et al., Sunvold '258, Jezek et al. and Desforges et al. all fail to teach the incorporation of beet pulp into a liquid composition, and wherein the composition is essentially free of sugars. Applicants argue that Desforges et al. disclose a sugar composition providing a source of soluble dietary fiber. However, the examiner respectfully argues that Burkhalter et al., Sunvold et al., Fahey et al., Sunvold '258, Jezek et al. and Desforges et al. all teach that beet pulp is a well-known source of dietary fiber important in maintaining animal health. Jezek et al. and Desforges et al. teach water-soluble fiber from beet pulp which can reduce serum cholesterol. Jezek et al. further teach that the soluble fraction from the sugar beet pulp can be used as a replacement for sugar (pg. 106, right column, paragraph numbered 7). Since it is well-known that beet pulp is an important source of dietary fiber important in maintaining animal health and the water-soluble fraction has a serum cholesterol lowering effect, it would have been *prima facie* obvious to one of ordinary skill in the art to use the water-soluble fraction of beet pulp in aqueous solutions being fed to animals, such as the aqueous compositions according to Chu et al.

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2. Claims 1-7 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tinembart et al. (US 2002/0058683) in view of Chu et al. (US 2002/0025325) and Burkhalter et al. (The Journal of Nutrition, 2001), Sunvold et al. (Journal of Animal Science, 1995), Fahey et al. (Journal of Animal Science, 1990), Sunvold '258 (US 5,932,258), Jezek et al. (Chemical and Biochemical Engineering Quarterly, 1996), and Desforges et al. (US 5,252,136).

Applicant's claims

Applicants claim a liquid composition comprising lufenuron, a flavorant and water, wherein the composition is essentially free of sugars or tomato flavor; as well as a kit comprising a plurality of compartmentalized containers housing said the composition.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Tinembart et al. teach a veterinary preparation for fleas comprising lufenuron and nitenpyram, wherein oral administration of a liquid composition comprising lufenuron and nitenpyram effectively controlled flea infestation ([0057]-[0058]). Tinembart et al. also teach that because of its simple practicability, oral usage is one of the preferred subjects of the invention, especially the administration of tablets or suspensions, wherein additives are used to encourage willing consumption by the host animal, such as suitable odorous substances, flavorings and/or taste substances ([0061]-[0063]). Tinembart et al. teach that the lufenuron and nitenpyram are present from 0.1-95 wt.% and a liquid, physiologically acceptable carrier is present from 99.9-5 wt.% ([0078]).

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Tinembart et al. teach that the dosages may be carried in specially designed packs for administration by the veterinarian or keeper ([0075] and [0087]).

Furthermore, Tinembart et al. teach an emulsifier concentrate example comprising 20 wt.% active substances (i.e. lufenuron and nitenpyram), 20 wt.% emulsifier, and 60 wt.% solvent, and the composition is diluted with water to the desired concentration (Example 6). Also, Tinembart et al. teach drink additive examples comprising 15 wt.% of active ingredient, 10 wt.% of the active ingredient in diethylene glycol monoethylether, 10 wt.% in polyethylene glycol 300, and 5 wt.% in glycerol (Example 7).

The teachings Chu et al. are discussed above and incorporated herein by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Tinembart et al. and Chu et al. do not teach adding beet pulp to their compositions, as instantly claimed. However, Burkhalter et al. teach that beet pulp is the most common source of fiber added to commercial dog diets (page. 1979, left column, lines 8-10 after the table description). Sunvold et al. teach that diets containing moderately fermentable fiber provide fermentation end products that may be important in maintaining the health of the gastrointestinal tract of the cat, and beet pulp represents a moderately fermentable fiber source (Abstract; pg. 2335, left column, last sentence; pg. 2338, left column, lines 40-55 without counting spaces). Fahey et al. teach beet pulp levels up to 7.5% of diet DM appear acceptable as a dietary fiber source in a meat-

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based canine diet (Abstract). Sunvold '258 teach beet pulp is a fermentable fiber which intestinal bacteria present in the animal can ferment to produce significant quantities of short-chain fatty acids (col. 3, ll. 48-54). Jezek et al. teach the production of soluble dietary fibers from sugar beet pulp (Title and Abstract). Desforges et al. teach water-soluble fiber obtainable by treating sugar beet with water free from chemical reagents at ambient temperature and at an elevated temperature (Abstract). Desforges et al. further teach that commercial sources of dietary fiber from sugar beet pulp are known, wherein araban is one example of a fraction of the soluble fiber from sugar beet, and water-soluble beet fiber is also found in beet molasses (col. 1, l. 55 to col. 2, l. 5). Desforges et al. also teach that soluble sugar beet fiber has cholesterol lowering properties (i.e., hypocholestromaemic effect), and a beneficial effect on blood glucose and mineral availability (col. 2, ll. 13-17).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to add beet pulp fiber to the composition of Tinembart et al. because beet pulp fiber is well-known as a commercial source of dietary fiber for use in pet foods, and soluble beet fiber has cholesterol lowering properties (i.e., hypocholestromaemic effect), and a beneficial effect on blood glucose and mineral availability, as reasonably taught by Desforges et al. Also, one of ordinary skill in the art would have been motivated to package the compositions in specially designed packs, or kits, for the veterinarian or keeper to administer the predetermined dosage at

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predetermined intervals, as reasonably taught by Tinembart et al. With regard to the instantly claimed kits comprising a plurality of compartments, it would have been *prima facie* obvious for one of ordinary skill in the art to provide a kit comprising multiple compartments in order to have several dosages within one pack or kit, which need to be administered according to a dosage scheme, as taught by Tinembart et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on page 10 that Burkhalter et al., Sunvold et al., Fahey et al., Sunvold '258, Jezek et al. and Desforges et al. all fail to teach the incorporation of beet pulp into a liquid composition, and wherein the composition is essentially free of sugars. Applicants argue that Desforges et al. disclose a sugar composition providing a source of soluble dietary fiber. However, the examiner's response to this argument is given above and incorporated herein by reference.

Applicants also argue on page 11 that Tinembart et al., Chu et al., Burkhalter et al., Sunvold et al., Fahey et al., Sunvold '258, Jezek et al. and Desforges et al., either alone or in combination, fail to teach kits comprising compartmentalized containers wherein a composition comprising a medicament is housed in a compartment that is separate from a compartment housing a composition comprising a flavorant, water, and

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is essentially free of sugars or tomato flavors. However, the examiner respectfully argues that, as instantly claimed, the medicament does not necessarily have to be separate from the flavorant and water. The 1st composition *comprising* a medicament within said 1st compartment, and the one or more compositions *comprise* of a flavorant and water within said compartment other than the 1st compartment, can be the same composition in two or more compartments. The 1st composition *comprising* a medicament housed in a 1st compartment can also contain other ingredients, such as flavorants and water; and the one or more compositions housed in a compartment of said container which is not said 1st compartment *comprise* of a flavorant and water and can also contain other ingredients, such as a medicament. Therefore, a composition comprising a medicament, flavorant, and water within two or more compartments within a kit would read on said claim.

The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) (“like the term ‘comprising,’ the terms ‘containing’ and ‘mixture’ are open-ended.”).[<] *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) (“The transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.”); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may

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be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616